

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

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[Docket No. 01N-0078]

**Agency Information Collection Activities; Submission for OMB Review; Comment Request; Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer (DTC) Promotion Drugs; Survey**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Submit written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Wendy Taylor, Desk Officer for FDA.

**FOR FURTHER INFORMATION CONTACT:** Karen L. Nelson, Office of Information Resources Management (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1482.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

## Assessment of Physician and Patient Attitudes Toward Direct-to-Consumer (DTC) Promotion Drugs; Survey

Under the Federal Food, Drug, and Cosmetic Act (the act), FDA is responsible for assuring that the labeling and advertising of prescription drugs is truthful and not misleading. Section 502(n) of the act (21 U.S.C 352(n)) prohibits the advertising of prescription drugs that is false or misleading or that fails to provide required information about product risks. Although advertising of prescription drugs was once primarily addressed to health professionals, consumers increasingly have become a primary target audience, and "direct-to-consumer" (DTC) advertising has dramatically increased in the past few years. However, DTC advertising raises many questions and issues. While it may alert consumers to new information and facilitate treatment of their medical problems, it also may confuse consumers and adversely impact the relationship between patients and their health care providers. In August 1997, when the agency issued its draft guidance on consumer directed broadcast advertisements, FDA announced that it would evaluate the effects of the guidance and of DTC promotion in general within 2 years of finalizing the guidance.

The guidance was finalized on August 9, 1999 (64 FR 43197). In the **Federal Register** notice announcing availability of the final guidance, FDA reiterated its intent to evaluate the effects of the guidance, including effects on the public health, within 2 years. As part of that evaluation, the agency conducted a baseline public information collection focused on recent patients, concerning the effects of DTC advertising on patient-doctor interactions and attitudes toward DTC advertising in general (OMB Control No. 0910-0399). The purpose of the proposed information collection is to followup on the agency's 1999 patient survey and expand information collection to include physicians. FDA needs information from physicians and patients about their reactions to, and behaviors that stem from, DTC prescription drug advertising in order to develop policy on appropriate requirements for regulating drug product promotional materials.

The collection effort will consist of two separate parts: A patient survey and a physician survey. The patient survey will be conducted through national randomized telephone interviews

with a national probability sample with 775 adults 18 years of age and over who have recently visited a physician. The sample will be limited to those respondents who have seen a doctor or other health care professional in the last 3 months. Patient respondents will be asked their views about any prescription drug they may have received and prescription drugs in general, and their attitudes and behavior in relation to DTC advertising. Demographic information will also be collected.

The physician survey will be conducted through telephone interviews with a national probability sample of office based physicians who engage in patient care at least half of the time. The sampling frame of physicians will consist of names drawn from the American Medical Association's physician masterfile. In an effort to maximize the response rate for physicians, prenotification letters will be mailed to all potential physician respondents. The survey itself will cover DTC-related patient interactions, perceived patient outcomes, attitudes toward appropriate DTC categories, and general opinions about DTC advertising. Demographic information will also be collected.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
11,625 (consumer screener)	1	11,625	.017	197.6
775 (consumer survey)	1	775	.333	258.1
3,333 (physician screener)	1	3,333	.017	56.7
500 (physician survey)	1	500	.250	125.0
Total				637.4

<sup>1</sup> There are no capital costs or operating and maintenance costs associated with this collection of information.

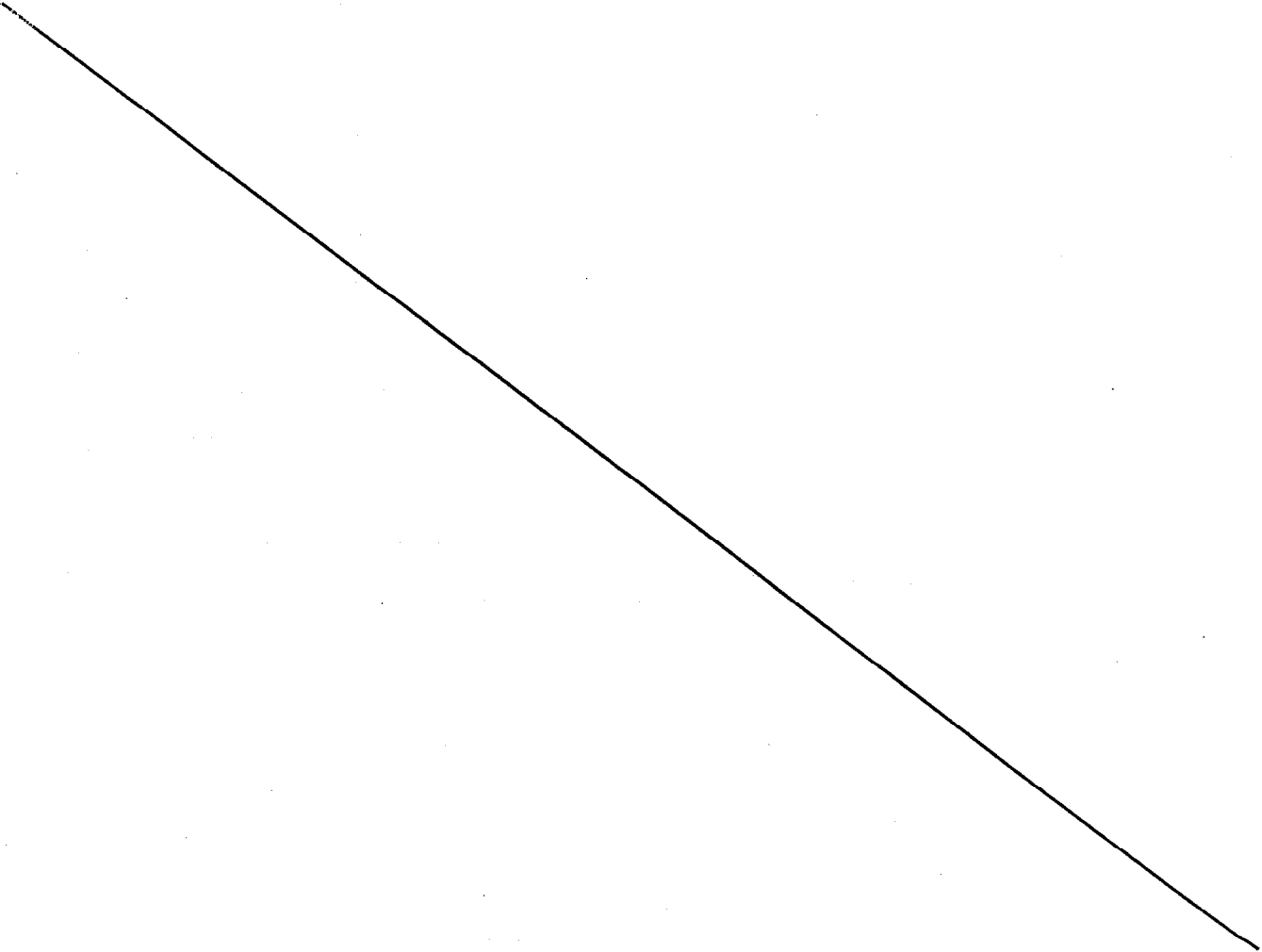
In the **Federal Register** of March 19, 2001 (66 FR 15494), the agency requested comments on the proposed collections of information. Comments were received from 31 organizations and individuals. The comments were grouped according to similarity.

1. Seven comments were unrelated to the proposed information collection.
2. Sixteen comments addressed general aspects of the information collection. Of these, 12 comments were supportive of the information collection as proposed. Four comments recommended a focus on behaviors rather than attitudes. This included two comments, which suggested a case

study design rather than a survey. We note that the proposed physician survey does ask the physician to focus on a specific event when answering questions about their interaction with a patient who had asked about a prescription drug, as well as any specific drugs that were discussed during the interaction. In addition, both the patient and physician surveys ask questions about the effect of DTC advertising on behaviors occurring during an office visit.

3. Eight comments addressed specific aspects of the questionnaire, including wording, sample, and additional areas of inquiry. The questionnaires were extensively revised to reflect these comments.

A pilot test of the questionnaires was conducted by the contractor to confirm estimates of timing, identify problems related to questionnaire wording and order of presentation, and ensure



that the questionnaire placed a minimal burden on respondents. The pretest included nine patient test respondents and nine physician test respondents. The pretest revealed that no substantive changes were necessary.

Dated: 8/7/01

August 07, 2001.

Margaret M. Dotzel

Margaret M. Dotzel,  
Associate Commissioner for Policy.

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